

C. Remarks

The claims are 6-9, 15, 17-19 and 25-27, with claims 6 and 15 being independent. Reconsideration of the present claims is expressly requested.

Initially, as a formal matter, the Examiner has noted that the status of claim 9 is not clear. Applicant has clarified that claim 9 is pending.

Claims 6, 7, 15, 17 and 19 stand rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by U.S. Patent Application Publication No. 2002/0110823 A1 (Hogan). Claims 8, 9 and 27 stand rejected under 35 U.S.C. § 103(a) as being allegedly obvious from Hogan in view of U.S. Patent No. 6,362,004 B1 (Noblett). Claims 18 and 25 stand rejected under 35 U.S.C. § 103(a) as being allegedly obvious from Hogan in view of U.S. Patent No. 5,876,926 (Beecham). Claim 26 stands rejected under 35 U.S.C. § 103(a) as being allegedly obvious from Hogan in view of U.S. Patent Application Publication No. 2001/0012537 A1 (Anderson). The grounds of rejection are respectfully traversed.

Prior to addressing the merits of rejection, Applicant would again like to briefly review some of the features and advantages of the presently claimed invention. That invention, in pertinent part, is related to a method for using a DNA microarray to both analyze a specimen collected from a subject and to identify the subject. To achieve this goal, the DNA microarray contains at least two DNA probe groups. The first DNA probe group can be used to distinguish a subject providing a specimen and a second DNA probe group can be used to test the specimen from the subject, so as to distinguish the subject and generate test information from the specimen. As a result, according to the present invention, both the identification of the test subject and a test for a disease can be

performed using the same sample (specimen) at the same time without the subject being present for identification purposes or using any other means of identifying the subject.

Hogan is directed to methods for genomic screening of subjects. Specifically, Hogan teaches detecting a genetic marker indicative of a response to anesthesia and other perioperative or operative treatments and procedures to determine low-risk medication and/or surgical technique.

The Examiner has alleged that Hogan teaches a method in which a sample specimen is used to identify a subject and to generate information on the course of treatment for the subject, wherein the specimen is analyzed using a DNA microarray comprising a set of probes that are used to distinguish a subject and a set of probes that are used to test a specimen from the subject. The Examiner pointed to paragraph [0134] in Hogan for the teaching related to the identification of the subject.

Paragraph [0134] in Hogan recites:

In some embodiments, additional markers are included that are not specific for the surgical procedure being performed, but that predict general outcome of surgery and related procedures. Examples include, but are not limited to markers for aminoglycoside ototoxicity, APOe4, wound cytokines, sepsis risk (TNF α), blood groups, coagulation factors, and thrombosis risk. In some embodiments, the perioperative screening assay includes other tests unrelated to the genomic profile for the main surgical application, but relevant in the case of a complication requiring emergency intervention (e.g., blood typing). In some embodiments, the perioperative genomic profile includes a unique genomic identifier (e.g., a series of polymorphic non-coding SNPs), thus providing a secure, accurate internal reference for archiving and tracking genetic data specific to the particular subject.

Thus, by referring to a “unique genomic identifier” or “genetic data specific to the particular subject”, Hogan does not teach distinguishing the subject by using a unique genomic identifier. The unique genomic identifier provides an internal reference indicative, for example, of a place of the gene to be observed. In other words, the unique genomic identifier in Hogan does not distinguish a subject, it distinguishes data.

Hogan refers to a DNA chip at paragraphs [0167]-[0176]. However, Hogan fails to disclose or suggest associating the unique genomic identifier with a probe on the DNA chip. Furthermore, Hogan fails to disclose or suggest a probe group for identifying a subject.

Also, Hogan describes an information card containing genetic information. However, Hogan merely teaches making the card hold genetic information, and fails to disclose or suggest utilizing such information card for distinguishing the subject. Accordingly, it is clear that Hogan cannot affect the patentability of the presently claimed invention.

Beecham cannot provide the teachings missing in Hogan. Beecham is directed to a method and an apparatus for obtaining biometric data from a test subject for identification and testing a sample obtained from the test subject. However, as acknowledged previously by the Examiner, Beecham fails to disclose or suggest performing these two processes using a single microarray.

Noblett and Anderson cannot cure the deficiencies of Hogan and Beecham. Noblett was cited by the Examiner for a teaching of fiducial marks on a microarray. Anderson was cited for a teaching of using identifiers on microarrays. However, even if

assumed, *arguendo*, that these references contain the alleged teachings, they still lack the same disclosure that is missing in Hogan and Beecham.

In conclusion, Applicant respectfully submits that the cited references, whether considered separately or in any combination, fail to disclose or suggest the presently claimed elements.

Wherefore, withdrawal of the outstanding rejections and expedient passage to issue are respectfully requested.

Applicant's undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

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